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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,782	07/09/2003	Hugh H. Trout III	23660-00654	8569

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EXAMINER

PANTUCK, BRADFORD C

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary

Application No.

10/614,782

Applicant(s)

TROUT, HUGH H.

Examiner

Bradford C Pantuck

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on November 15, 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,10-13 and 15-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-8, 10-13, 15-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note*the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 3-8, 10-13, and 15-19 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,865,791 to Wayne. Regarding Claims 1, 8, and 13, Wayne discloses a delivery apparatus for performing a surgical procedure, including a flexible catheter (52/83), a penetration apparatus (66), and a fastener (116) in communication with (touching) the penetration apparatus [Figures 29, 32A, and 31C]. Pulling on steering mechanism (57) [see Fig. 29] causes the distal end of flexible catheter (52/83) to deflect to an angular configuration, as shown in Figure 7 of U.S. Patent No. 5,254,088 to Lundquist et al. Wayne incorporates the same steering mechanism (57) that was disclosed in this U.S. Patent No. 5,254,088 [Column 5, lines 50-54] into his device. Therefore, Wayne's delivery apparatus will deflect just as Lundquist's delivery device does.

Furthermore, Wayne's device has an outer catheter (112) and an inner catheter (114) [Column 12, lines 1-20]. The inner catheter is *disposed in* the outer catheter. The inner catheter and the outer catheter (and the whole catheter assembly) are movable, in that the whole assembly can be moved by the user: Column 11, lines 59-

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63 explains that the user can move the whole assembly axially (distally or proximally).

2. Regarding Claim 3, the tip of the penetration apparatus (66) is a hollow core needle [Figures 16A, 16B, 17, and 29; Column 7, lines 30-33].
3. Regarding Claims 4-6, 8, 10-12, and 15-17, Wayne discloses a sealant material/occluding substance/plug associated with the fastener [Column 12, lines 52-55]. The sealant material/occluding substance/plug can be material such as silicone, collagen, mesh or even clotted human blood, as described in said passage.
4. Regarding Claim 7, mesh is capable of absorbing water.
5. Regarding Claim 18, Wayne discloses a method of performing a surgical procedure at a surgical site, including advancing a delivery apparatus to the site in the body and activating the delivery apparatus to apply a fastener (116) to the surgical site [Column 12, lines 33-45; Figures 29 and 31A]. Fastener (116) in one embodiment [Fig. 31A, Fig. 31B] secures a surgical component (suture 126) to a vessel (16/17). The atrium/heart is considered a vessel, because it holds/carries blood.
6. Regarding Claim 19, Wayne's delivery apparatus includes a solid core ("stylet" 118) inside of penetration apparatus (66) [Fig. 29].

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Response to Arguments

8. Applicant's arguments filed November 15, 2004 have been fully considered but they are not persuasive. First, regarding Applicant's contention that Examiner "rejects the claims with a combination of references" [REMARKS, page 7, lines 14-15], Examiner disagrees. Although Applicant argues that Examiner rejected the claims with a combination of U.S. Patent No. 5,865,791 to Whayne *in view of* U.S. Patent No. 5,254,088 to Lundquist et al., Examiner contends that this is not the case. Whayne *single handedly* discloses each and every feature of the invention, *including a catheter having the ability to deflect*. Examiner made reference to Lundquist only to *clarify* and *show a more detailed view* of the means (57) used by Whayne to make his catheter deflect.
9. Regarding Examiner's maintaining his rejection under U.S. Patent No. 5,865,791 to Whayne, Examiner would like to clarify his position. Regarding the limitation "an

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inner catheter *movably disposed in* the outer catheter” [emphasis added], Applicant has not claimed an inner catheter that necessarily moves *relative to* the outer catheter. Whayne’s inner catheter (114) is disposed in the outer catheter (112), and is capable of moving. The Examiner must interpret the claims with the broadest reasonable interpretation. Furthermore, the limitation “a flexible catheter capable of assuming an angular configuration,” Applicant has not necessarily claimed only a catheter that deflects to form two parts that are at an angle relative to each other. The said limitation would include any flexible catheter, whose body can be rotated relative to another piece of surgical equipment. Examiner suggests that Applicant use more precise language to define the invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (571) 272-4701. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BCP
BCP
January 5, 2005


ANH TUANT. NGUYEN
PRIMARY EXAMINER
1/7/05